

REMARKS

I. Status of Claims

Currently, claims 1, 3, 10-12, 14, 20, 22-26, and 30-51 are pending in this application, claims 23-26 and 30-35 having been withdrawn by the Office as directed to a non-elected invention.

Claims 1, 12, 36, 40, 44, 48, 49, and 50 have been amended to recite that the “second enzyme is the wild type Pfu DNA polymerase identified at Accession No. P80061 . . .” Support for this amendment can be found throughout the specification, including, for example, at page 15 (Table 1). Claims 1, 12, 36, 40, 44, 48, 49, and 50 have been amended to recite that the second enzyme has reduced 5' – 3' DNA polymerization activity “as compared to the wild type Pfu DNA polymerase.” Support for this amendment can be found throughout the specification, including, for example, at page 9, lines 9-12. No new matter is added.

II. Rejection Under 35 U.S.C. §112, Second Paragraph

The Office rejects claims 1, 3, 10, 11, 12, 14, 20, 22, and 36-51 under § 112, second paragraph as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. Office Action at 2. Specifically, the Office asserts that “[r]eference to Y410, T542, D543, K593, Y585, Y385, G387 and G388 is a relative to an amino acid sequence and absent a reference amino acid sequence such reference is indefinite.” *Id.* at 2-3. The wild type Pfu DNA polymerase was known as of Applicants’ filing date. Therefore, it is not necessary to recite the actual sequence or an accession number in the

claims because one of skill in the art would understand the metes and bounds of the claim.

Nevertheless, solely in an effort to expedite prosecution, Applicants have amended claims 1, 12, 36, 40, 44, 48, 49, and 50 to recite that the “wild type Pfu polymerase identified at Accession No. P80061 . . .” Accordingly, Applicants respectfully request that the Office withdraw this rejection.

III. Rejection of Claims 31-43 Under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 48-51 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and as lacking enablement. (Office Action at pages 3-9.) More specifically, the Office states that the claims are directed to kits comprising Pfu DNA polymerases having mutations outside of those specifically recited in the claims. Applicants traverse this rejection and submit that the Office has misinterpreted the claim language.

Independent claims 48-50 recite the phrase “at least one amino acid position selected from the group consisting of” followed by a specific recitation of various amino acids/positions within an enzyme. This claim language is standard “Markush”-type language used in U.S. patent practice, and specifically approved by the M.P.E.P. (see M.P.E.P. § 2173.05(h)). As stated in the M.P.E.P., claiming using a “Markush” group is a manner of claiming “a genus expressed as a group consisting of certain specified materials.” Within the context of the present claims, the genus is a mutated enzyme specified as having at least one of a well-defined number of specific mutations. The present claim language, and in particular the phrase “at least one,” indicates to

those of skill in the art that the genus described by the “Markush” group is not limited to enzymes with single mutations, but to enzymes having one or multiple mutations selected from the recited group. The claims clearly indicate which mutation or mutations are within the literal scope of the group from which mutations may be selected, and the claim language cited by the Office does not relate to mutations outside of those specifically recited in the “Markush” group.

In contrast to the clear language and meaning of the claims, in setting forth the rejection, the Office has parsed the phrase “at least one amino acid position selected from the group consisting of” into two separate and distinct phrases: “at least one” and “amino acid position selected from the group consisting of.” Specifically, the Office interprets the phrase “at least” in the context of claims 48-50 “as allowing additional mutations outside the referenced positions, such that applicants have not adequately described [or enabled] this genus.” Office Action mailed 13 November 2007 at 5 and 7.

Applicants submit that doing so is improper because it is inconsistent with the clear meaning of the claim language. It is also inconsistent with controlling case law from the Federal Circuit. As the Federal Circuit has recognized, a patent applicant may expressly indicate that a claim covers a combination of the recited Markush members by using language such as “and mixtures thereof” or “at least one member” in the Markush group. That is precisely what Applicants have done here. As noted in *Abbott Labs. v. Baxter Pharmaceutical Prods., Inc.*, 334 F.3d 1274, 1281, (Fed. Cir. 2003), “[i]f a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim.” Citing to the “Meeting Held to Promote Uniform Practice In Chemical

Divisions,” 28 J. Pat. & Trademark Off. Soc’y 849, 852 (1946), the Federal Circuit recognized examples of qualifying language in Markush groups that was approved by the USPTO, including “and mixtures thereof” and “at least one member of the group.” *Id.* Thus, as acknowledged by the Federal Circuit, it has long been common practice to use expressions like “at least one” in the context of Markush language to indicate that the claim covers one or more members of the recited Markush group.

This reasoning has also been followed by at least one district court. In *Dow Agrosciences LLC v. Cromopton Corp.*, No. 1:03-CV-0654-SEB-JPG, 2004 WL 1087362, *7 (S.D. Ind. May 12, 2004), the district court found that a claim limitation reciting “the phenyl group contains *at least one* substituent chosen from the group consisting of:” permitted a combination of members from the group. Specifically, the court stated that

[i]f a patentee desires to use or to combine multiple members of the Markush group, then he or she must add qualifying language to the claim. An example of such qualifying language is ‘at least one member of the group.’ Therefore, in our case, the language ‘at least one’ and ‘chosen from the group consisting of’ in our judgment modifies the word substituent, allowing the patentee to select more than one substituent from among the Markush group.

Id.

Accordingly, Applicants submit that the Office’s interpretation of the Markush language at issue is incorrect and its position on written description and enablement moot. Rather, the correct claim interpretation must be that discussed above, which is fully consistent with U.S. law, U.S. patent regulations, and USPTO examination guidelines. For at least this reason, Applicants

request that the Office reconsider and withdraw the rejection of claims 48-51 under 35 U.S.C. § 112, first paragraph.

IV. Double Patenting Rejections

The Office provisionally rejects claims 1, 3, 10-12, 14, 20, 22, and 36-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-70 and 75-87 of copending U.S. Patent Application No. 10/079,241. (Office Action at 9-10.) Applicants acknowledge this provisional rejection and request that the Office hold the rejection in abeyance until one or the other application is in condition for allowance. At that time, Applicants will file a Terminal Disclaimer in the application that has yet to be allowed, if necessary at that time.

V. **Conclusion**

In view of the foregoing amendment and remarks, Applicants submit that this application is in condition for allowance. Applicants therefore request entry of this amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this paper and charge any additional required fees to Deposit Account No. 50-3740.

Respectfully submitted,
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